October 31, 2023

Alesi Surgical Ltd.
℅ Michele Lucey
President
Lakeshore Medical Device Consulting
128 Blye Hill Landing
Newbury, New Hampshire 03255

Re: K231298
Trade/Device Name: Ultravision2™ System Integrated Monopolar L-Hook (H/S)™
Regulation Number: 21 CFR 878.5050
Regulation Name: Surgical Smoke Precipitator
Regulatory Class: Class II
Product Code: PQM, GEI
Dated: May 2, 2023
Received: May 4, 2023

Dear Michele Lucey:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Christopher K. Dugard -S

Christopher K. Dugard, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical

and Infection Control Devices
Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
k231298

Device Name
Ultravision2™ System Integrated Monopolar L-Hook (H/S)™.

Indications for Use *(Describe)*

The Ultravision 2™ Integrated Monopolar L-Hook (H/S)™ is intended to be used with applications in surgical procedures to facilitate cutting, coagulating of tissue, in combination with the clearance of smoke and other particulate matter that is created during laparoscopic surgery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**K231298**

**510(K) SUMMARY**
**TRADITIONAL**
**As required by 21 CFR 807.92**

| | |
|---|---|
| **Submitter Information:** | |
| **Submitter's Name:** | Alesi Surgical Ltd |
| **Address:** | Cardiff Medicentre<br>Heath Park<br>Cardiff<br>CF14 4UJ<br>UK |
| **Telephone:** | +44 (0) 2920291022 |
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| **Contact Person:** | Michele Lucey<br>Lakeshore Medical Device Consulting LLC.<br>128 Blye Hill Landing.<br>Newbury,<br>New Hampshire 03255 |
| **Telephone:** | 603-748-1374 |
| **Date Prepared:** | October 31, 2023 |
| **Device Proprietary Name:** | Ultravision2™ Integrated Monopolar L-Hook(H/S) ™ |
| **Common Name:** | Surgical Smoke Precipitator |
| **Classification Name:** | Surgical Smoke Precipitator |
| **Classification Regulation:** | 21 CFR 878.5050 |
| **Product Code:** | PQM |
| **Common Name:** | Electrosurgical accessory, laparoscopic electrode |
| **Classification Regulation:** | 21 CFR 878.4400 |
| **Product Code:** | GEI |
| **Regulatory Class:** | Class II |
| **Predicate Device:** | Ultravision™ Visual Field Clearing System (K200035)<br>Covidien Laparoscopic Handset K964175 and<br>Clean Coat™ Laparoscopic Wire L-Hook Monopolar Electrode K153265 (electrode) |

**Indications for Use:**

The Ultravision 2™ Integrated Monopolar L-Hook (H/S)™ is intended to be used with applications in surgical procedures to facilitate cutting, coagulating of tissue, in combination with the clearance of smoke and other particulate matter that is created during laparoscopic surgery.

**Device Description/Technological Characteristics:**

The Integrated Monopolar L-Hook (H/S)™ is a bifunctional device that combines proprietary visual field clearing and monopolar HF tissue and coagulation in a single device.

The Integrated Monopolar L-Hook (H/S)™ can only interface with the Ultravision2 generator which connects directly to a commercially available electrosurgical generator (ESU) for its HF monopolar energy source. The Integrated Monopolar L-Hook (H/S)™ provides two recessed smoke clearing emitters that are automatically activated to clear the visual field when the device cutting function (HF) is activated. The mode of action of visual field clearing is electrostatic precipitation as per the predicate Ultravision system. When the tissue cutting is ceased, the visual field clearing signal is automatically switched off after a short delay period that is settable on the Ultravision 2 generator user interface.

Activation of the HF function of the Integrated Monopolar L-Hook (H/S)™ is via a yellow (Cut) or blue (Coag) button located on the handpiece, or via a footswitch if this connected to the parent electrosurgical generator which is connected to the Ultravision 2 system. The Integrated Monopolar L-Hook (H/S)™ itself is incompatible with the connectors of third party electrosurgical generators.

On demand visual field clearing only can also be applied by activation of a third grey button on the handle. This clearing field action is stopped immediately after release of the grey button.

The Integrated Monopolar L-Hook (H/S)™ is available with a working length of 32cm. It is intended to be introduced via standard 5mm surgical trocars as long as their internal diameter is 5.70mm or greater. The device is for prescription use only.

When used with the Ultravision2 generator the components of the system will be:

| **Model #** | **Component Description** |
|---|---|
| DPD-006-001 | Ultravision2™ System, including:<br>• Standalone generator<br>• Link cables (monopolar and return)<br>• Equipotential cable<br>• Power cable |
| DPD-006-201 | The Integrated Monopolar L-Hook (H/S)™ |

**Technological Characteristics Comparison:**

The comparison table below provides the similarities and differences between the predicate and subject devices. The modifications made to the subject device do not raise any risk to safety or effectiveness.

| **Technical Characteristics Comparison Table** | | | | |
|---|---|---|---|---|
| Feature/ Specification | Integrated Monopolar L-Hook™ Subject Device | Ultravision Visual Field Clearing System (UV1) Predicate 1 | Covidien Laparoscopic Handset with CleanCoat™ Laparoscopic Wire L-Hook Monopolar Electrode Predicate 2 | Comparison |
| Regulatory Clearance/ Approval Reference | K231298 | K200035 | K964175 (handpiece) K153265 (electrode) | N/A |
| Product Code(s) | PQM GEI | PQM | GEI | Equivalent |
| Regulation Number(s) | 878.5050 878.4400 | 878.5050 | 878.4400 | Equivalent |
| Regulation Name(s) | Surgical Smoke Precipitator AND Electrosurgical Cutting &Coagulation & Accessories | Surgical Smoke Precipitator | Electrosurgical Cutting &Coagulation & Accessories | Equivalent |
| Where used (environment) | Laparoscopic surgery | Surgery, including laparoscopic surgery | Minimally invasive surgical procedures including laparoscopic and thoracoscopic | Equivalent |
| Anatomical Sites | Abdominal and pelvic cavity. | Abdominal and pelvic cavity. | Abdominal and pelvic cavity. | Equivalent |
| Target population | General patients requiring electrosurgery in a hospital setting | General patients requiring electrosurgery in a hospital setting | General patients requiring electrosurgery in a hospital setting | Equivalent |

| Technical Characteristics Comparison Table | | | | |
|---|---|---|---|---|
| Feature/ Specification | Integrated Monopolar L-Hook™ Subject Device | Ultravision Visual Field Clearing System (UV1) Predicate 1 | Covidien Laparoscopic Handset with CleanCoat™ Laparoscopic Wire L-Hook Monopolar Electrode Predicate 2 | Comparison |
| Current | Ionwand- intermittent max 20µA<br>Integrated L-Hook instrument- 2 x 20µA intermittent max | Continuous max 10µA | N/A | Similar<br>This difference does not raise new questions of safety and effectiveness., confirmed through standardized electrical safety testing |
| Visual field clearing mechanism of action | Electrostatic Precipitation | Electrostatic Precipitation | NA | Equivalent |
| Ionwand tip material | Implant grade Stainless steel, annealed | Implant grade Stainless steel, annealed. | N/A | Equivalent |
| Ionwand energy modality | HVDC | HVDC | N/A | Equivalent |
| Ionwand working length | N/A- integrated into instrument - refer to electrode working length | 109mm | N/A | Similar feature but different dimension |
| Handpiece Electrode modality | Monopolar for electrosurgery<br>HVDC for visual field clearance | N/A | Monopolar for electrosurgery | Equivalent |
| Handpiece Operation Principle | Colored and segregated finger switches for<br>a) Cutting (yellow)<br>b) Coagulation (blue)<br>c) Smoke precipitation (grey) | NA | Rocker switch for<br>a) Cutting (yellow)<br>b) Coagulation (blue)<br>c) Vacuum control – 2 buttons<br>d) Irrigation port | Equivalent RF controls<br>Both include smoke clearing<br>The absence of irrigation in Ultravision 2 does not raise new questions about safety and |

| Technical Characteristics Comparison Table | | | | |
|---|---|---|---|---|
| Feature/ Specification | Integrated Monopolar L-Hook™ Subject Device | Ultravision Visual Field Clearing System (UV1) Predicate 1 | Covidien Laparoscopic Handset with CleanCoat™ Laparoscopic Wire L-Hook Monopolar Electrode Predicate 2 | Comparison |
| | | | | effectiveness |
| Handpiece physical and dimensional characteristics | Includes electrode and handpiece in an integrated form | N/A | Comprises separate handpiece and electrode | Equivalent in an integrated form |
| Electrode Working length | 32cm | N/A | 36cm & 45cm<br>32cm when connected to the handset | Equivalent |
| Handpiece shaft and shaft insulation materials | Stainless steel shaft, fluoropolymer shaft insulation | NA | Stainless steel shaft, polyolefin shaft insulation | Commonly used insulation materials used |
| Handpiece total electrode resistance (tip to plug) | 1Ω max | N/A | Less than 100 mΩ | Similar |
| Electrode tip insulation | PTFE electrode tip insulation<br>PTFE coated electrode | | PTFE electrode tip insulation, non-coated electrode, and PTFE coated electrode | Equivalent |
| Handpiece tip design | L- wire, stainless steel 17-7PH | N/A | L-wire, stainless steel | Equivalent |
| Handpiece performance | Performs cut and coagulation in electrosurgical procedures<br>AND<br>Visual field clearing | Visual field clearing | Performs cut and coagulation in electrosurgical procedures and smoke evacuation and irrigation | Similar except for suction which is not needed for Ultravison. The absence of irrigation in the subject device does not raise new questions about safety and effectiveness |
| Handpiece compatibility | Compatible with 5mm cannular or larger | N/A | Compatible with electrosurgical with 0.093” nozzle and with 5mm cannula or | The difference in generator compatibility does not raise new |

| Technical Characteristics Comparison Table | | | | |
|---|---|---|---|---|
| Feature/ Specification | Integrated Monopolar L-Hook™ Subject Device | Ultravision Visual Field Clearing System (UV1) Predicate 1 | Covidien Laparoscopic Handset with CleanCoat™ Laparoscopic Wire L-Hook Monopolar Electrode Predicate 2 | Comparison |
| | Compatible with the Ultravision2™ Generator | | larger<br>Compatible with Valleylab RF energy platforms | questions of safety and effectiveness |
| How Supplied (single use) | Integrated handpiece - supplied sterile in single blister pack or pouch | Ionwand, trocar - supplied sterile in single blister or pouch | Supplied sterile in single pouches | Equivalent |
| Biocompatibility | Meets ISO 10993 Part 5,10 and 11 | Meets ISO 10993 Part 5,10 and 11 | Assume biocompatibility was demonstrated | Equivalent |
| Sterilization | EtO | EtO | Gamma Irradiation | All use standard sterilization modalities |
| Sterility Assurance Level | $10^{-6}$ | $10^{-6}$ | $10^{-6}$ | Equivalent |
| Mechanism of action of visual field clearance | Electrostatic precipitation | Electrostatic precipitation | NA | Equivalent |

**Summary of Non-clinical Testing:**

Testing demonstrated acceptable device performance for the device's intended use. System verification and validation activities were successfully completed as follows:

| Test Performed | Standard Followed | Acceptance Criteria | Results |
|---|---|---|---|
| Electrical safety and electromagnetic compatibility in accordance with IEC 60601-1, | IEC 60601-1 Medical Electrical Equipment, Edition 3.1, which is Edition 3.0 (2005-12) as modified by AM1 (2012-07) evaluation. | Device must meet the requirements of the applicable clauses in the standards | Pass |
| IEC 60601-2-2, IEC 60601-1-2 including capacitive coupling assessment. | IEC 60601-2-2 High Frequency Surgical Equipment (2017-03) evaluation<br>EN 60601-1-2:2015 + A1:2021 Medical electrical equipment | Device must meet the requirements of the applicable clauses in the standards | Pass |

| Test Performed | Standard Followed | Acceptance Criteria | Results |
|---|---|---|---|
| | General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances | | |
| Shelf Life | ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Medical Device Packages<br>ASTM 2096 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization<br>ASTM F88/F88M -15 Standard Test Method for Seal Strength of Flexible Barrier Materials | Product and package must demonstrate stability for the claimed shelf life of six months. | Pass |
| Mechanical robustness of device | NA | Device must meet mechanical specification per internal standards. | Pass |
| General, visual, dimensional and electrical verification of instrument | NA | Device must meet dimensional, electrical, and physical specifications per internal standards. | Pass |
| Visual field clearing (surgical smoke removal) | NA | Device must meet performance specifications per the internal standards. | Pass |
| Electrical bench tests | NA | Device must meet electrical performance and safety specifications per the internal standards. | Pass |
| Assessment of thermal depth of margin | NA | The thermal margin must be substantially equivalent to the predicate device in terms of its potential for tissue damage | Pass |
| Design validation under simulated use conditions | NA | Device must achieve its intended use when used by end users and that performance is at least equivalent to the predicate device | Pass |

**Biocompatibility**

The tissue contacting components of the Integrated Monopolar L-Hook (H/S)™ are substantially equivalent to the material and process to the predicate devices. Biocompatibility testing was performed to demonstrate that the device is biocompatible. The following testing was completed with acceptable results:

| Test Name | Standard | Acceptance Criteria | Pass/Fail |
|---|---|---|---|
| Cytotoxicity | ISO 10993-5: 2009 | Under the condition of the test, the test article must be non-cytotoxic | Pass |
| Skin Irritation Study in Rabbits | ISO10993-11: 2017 | Under the condition of the test, the test article must be non-irritating. | Pass |
| Systemic Toxicity in Mice | ISO 10993-10: 2021 | Under the condition of the test, the test article must not elicit evidence of systemic toxicity. | Pass |
| Guinea Pig Maximization Sensitization Test | ISO 10993-10: 2021 | Under the condition of the test, the test article must be non-sensitizing. | Pass |
| Hemolysis | ISO 10993-4: 2017 | Under the condition of the test, the test article must be non-hemolytic. | Pass |
| Material Mediated Pyrogens | USP General Chapter <151> | Under the condition of the test, the test article must be non-pyrogenic | Pass |

## Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in this 510(k) submission, K231298 is as safe, as effective, and performs as well as or better than the legally marketed predicate devices cleared under K200035, Class II (21 CFR 878.5050), product code PQM, and K153265, K964175, Class II (21 CFR 878.4400), product code GEI.